



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Jami Miller, Regulatory Affairs
Alfred Mann Foundation
25134 Rye Canyon Loop, Suite 200
Santa Clarita, CA 91355

Date: July 6, 2010
In response refer to: F2008-3514

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Requester:

In response to your request (copy enclosed) for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act:

- ☐ After searching our files, we did not find the requested records.
- ☐ We have no disclosable information as requested.
- ☒ We are enclosing the requested record(s). P890055, P800036, P860004 SSED's
- ☐ This is a partial response. Further response will be made.

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

Food and Drug Administration
Freedom of Information Staff
10903 New Hampshire Avenue
WO66-5262
Silver Spring, MD 20993-0002

"Should the agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal."

- ☒ The following charges will be included in a monthly invoice:

Reproduction: \$1.00 Search: \$46.00 Review: \$46.00 Other: \$0.00 Total: \$93.00

- ☐ See addendum for comment(s).

The above total may not reflect final charges for this request. Please **DO NOT** send payment unless you secure an invoice for the total monthly fee. If I can be of further assistance please contact me at (301) 796-5954 or email me at Susan.Weeks@fda.hhs.gov.

Sincerely yours,

Susan M. Weeks
Consumer Safety Officer
Freedom of Information Branch
Office of Management Operations
Center for Devices and Radiological Health
Food and Drug Administration